TITLE 22. EXAMINING BOARDS
Part 15. Texas State Board of Pharmacy
Chapter 291. Pharmacies
Subchapter B. Community Pharmacy (Class A)

22 TAC §291.31, §291.32, §291.33, §291.34

The Texas State Board of Pharmacy proposes amendments to §291.31 concerning Definitions, §291.32 concerning Personnel, §291.33 concerning Operational Standards, and §291.34 concerning Records in a Class A (Community) Pharmacy. The amendments to §§291.31-291.33, if adopted, will remove the current provisions relating to compounding of non-sterile and sterile pharmaceuticals and reference new sections §291.25 and §291.26 which outline new provisions for the compounding of non-sterile and sterile pharmaceuticals. The amendments to §291.34, if adopted, will specify that only a pharmacist may verify the receipt of controlled substances by a pharmacy.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state government as a result of enforcing or administering the rule. There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be the establishing of standards for the compounding of non-sterile and sterile pharmaceuticals by pharmacies and stricter controls on the receipt of controlled substances by pharmacies. There is no fiscal impact anticipated for small or large businesses or to other entities who are required to comply with this section.

A public hearing to receive comments on the proposed amendments will be held at 9:00 a.m. on Tuesday, November 18, 2003, at the Health Professions Council Board Room, 333 Guadalupe Street, Tower II, Room 2-225, Austin, Texas 78701. Persons planning to present comments to the Board are asked to provide a written copy of their comments prior to the hearing or bring 20 copies to the hearing. Written comments on the amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, 333 Guadalupe Street, Suite 3-600, Austin, Texas, 78701, FAX: 512/305-8082, E-mail: allison.benz@tsbp.state.tx.us. Comments must be received by 5 p.m., November 12, 2003.

The amendments are proposed under sections 551.002 and 554.051(a) of the Texas Pharmacy Act (Chapters 551-566 and 568-569, Texas Occupations Code). The Board interprets section 551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets section 554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this rule: Chapters 551-566 and 568-569, Texas Occupations Code.

The agency hereby certifies that the proposed amendments have been reviewed by legal counsel and found to be a valid exercise of the agency's authority.

§291.31 Definitions.
The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (8) (No Change.)

[~~(9) Component - Any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product.~~

~~(10) Compounding - The preparation, mixing, assembling, packaging, or labeling of a drug or device:~~

~~(A) as the result of a practitioner's prescription drug order or initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;~~

~~(B) in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns; or~~

~~(C) for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale or dispensing.~~]

(9) [~~(11)~~] Confidential record - Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist, such as a patient medication record, prescription drug order, or medication order.

(10) [~~(12)~~] Controlled substance - A drug, immediate precursor, or other substance listed in Schedules I-V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedules I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(11) [~~(13)~~] Dangerous drug - Any drug or device that is not included in Penalty Groups 1-4 of the Controlled Substances Act and that is unsafe for self-medication or any drug or device that bears or is required to bear the legend:

(A) - (B) (No change.)

(12) [~~(14)~~] Data communication device - An electronic device that receives electronic information from one source and transmits or routes it to another (e.g., bridge, router, switch or gateway).

(13) [~~(15)~~] Deliver or delivery - The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(14) [~~(16)~~] Designated agent -

(A) -(D) (No Change.)

(15) [~~(17)~~] Dispense - Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(16) [~~(18)~~] Dispensing pharmacist - The pharmacist responsible for the final check of the dispensed prescription before delivery to the patient.

(17) [~~(19)~~] Distribute - The delivery of a prescription drug or device other than by administering or dispensing.

(18) [~~(20)~~] Downtime - Period of time during which a data processing system is not operable.

(19) [~~(21)~~] Drug regimen review - An evaluation of prescription drug orders and patient medication records for:

(A) - (J) (No Change.)

(20) [~~(22)~~] Electronic prescription drug order - A prescription drug order which is transmitted by an electronic device to the receiver (pharmacy).

(21) [~~(23)~~] Electronic signature - A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) -(B) (No Change.)

(22) [~~(24)~~] Full-time pharmacist - A pharmacist who works in a pharmacy from 30 to 40 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(23) [~~(25)~~] (25) Hard copy - A physical document that is readable without the use of a special device (i.e., cathode ray tube (CRT), microfiche reader, etc.).

[~~(26) Manufacturing - The production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of the container and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons but does not include compounding.~~]

(24) [~~(27)~~] Medical Practice Act - The Texas Medical Practice Act, Subtitle B, Occupations Code, as amended.

(25) [~~(28)~~] Medication order - A written order from a practitioner or a verbal order from a practitioner or his authorized agent for administration of a drug or device.

(26) [~~(29)~~] New prescription drug order - A prescription drug order that:

(A) - (C) (No Change.)

(27) [~~(30)~~] Original prescription - The:

(A) - (B) (No Change.)

(28) [~~(31)~~] Part-time pharmacist - A pharmacist who works less than full-time.

(29) [~~(32)~~] Patient counseling - Communication by the pharmacist of information to the patient or patient's agent in order to improve therapy by ensuring proper use of drugs and devices.

(30) [~~(33)~~] Pharmaceutical care - The provision of drug therapy and other pharmaceutical services intended to assist in the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

(31) [~~(34)~~] Pharmacist-in-charge - The pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(32) [~~(35)~~] Pharmacy technician - Those individuals utilized in pharmacies whose responsibility it shall be to provide technical services that do not require professional judgment concerned with the preparation and distribution of drugs under the direct supervision of and responsible to a pharmacist. Pharmacy technician includes certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees.

(33) [~~(36)~~] Pharmacy technician trainee - A pharmacy technician:

(A) -(B) (No Change.)

(34) [~~(37)~~] Physician assistant - A physician assistant recognized by the Texas State Board of Medical Examiners as having the specialized education and training required under Subtitle B, Chapter 157, Occupations Code, and issued an identification number by the Texas State Board of Medical Examiners.

(35) [~~(38)~~] Practitioner -

(A) - (C) (No Change.)

(D) does not include a person licensed under the Texas Pharmacy Act.

(36) [~~(39)~~] Prepackaging - The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container into a prescription container for dispensing by a pharmacist to the ultimate consumer.

(37) [~~(40)~~] Prescription drug order -

(A) - (B) (No Change.)

(38) [~~(41)~~] Prospective drug use review - A review of the patient's drug therapy and prescription drug order or medication order prior to dispensing or distributing the drug.

(39) [~~(42)~~] State - One of the 50 United States of America, a U.S. territory, or the District of Columbia.

(40) [~~(43)~~] Texas Controlled Substances Act - The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(41) [~~(44)~~] Written protocol - A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas State Board of Medical Examiners under the Texas Medical Practice Act.

§291.32 Personnel

(a) *Pharmacist-in-charge.*

(1) (No Change.)

(2) *Responsibilities*. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(A) - (C) (No Change.)

~~[(D) bulk compounding of drugs;]~~

(D) [~~(E)~~] storage of all materials, including drugs, chemicals, and biologicals;

(E) [~~(F)~~] maintaining records of all transactions of the Class A pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials required by applicable state and federal laws and sections;

(F) [~~(G)~~] supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs;

(G) [~~(H)~~] adherence to policies and procedures regarding the maintenance of records in

a data processing system such that the data processing system is in compliance with Class A (community) pharmacy requirements;

(H) [~~(I)~~] legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy; and

(I) [~~(J)~~] effective September 1, 2000, if the pharmacy uses an automated pharmacy dispensing system, shall be responsible for the following:

(i) - (v) (No Change.)

(b) (No Change.)

(c) *Pharmacists.*

(1) - (2) (No Change.)

(3) *Special requirements for [~~nonsterile~~] compounding.*

(A) ***Non-Sterile Pharmaceuticals.*** All pharmacists engaged in compounding **non-sterile pharmaceuticals** shall **meet the training requirements specified in §291.25 of this title (relating to Pharmacies Compounding Non-sterile Pharmaceuticals).** [~~possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised. Continuing education shall include training in the art and science of compounding and the legal requirements for compounding.~~]

(B) ***Sterile Pharmaceuticals.*** **All pharmacists engaged in compounding non-sterile pharmaceuticals shall meet the training requirements specified in §291.26 of this title (relating to Pharmacies Compounding Sterile Pharmaceuticals).** [~~A pharmacist shall inspect and approve all components, drug product containers, closures, labeling, and any other materials involved in the compounding process.~~]

~~(C) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to assure that errors have not occurred in the compounding process.~~

~~(D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.~~]

(d) *Pharmacy Technicians.*

(1) Qualifications.

(A) - (C) (No Change.)

(D) ***Special requirements for compounding.***

(i) ***Non-Sterile Pharmaceuticals.*** **All pharmacy technicians engaged in compounding non-sterile pharmaceuticals shall meet the training requirements specified in §291.25 of this title (relating to Pharmacies Compounding Non-sterile Pharmaceuticals).**

(ii) ***Sterile Pharmaceuticals.*** **Pharmacy technicians may compound sterile pharmaceuticals pursuant to medication orders provided the pharmacy technicians:**

(I) are certified pharmacy technicians or technician trainees;

(II) have completed the training specified in subsection (f) of this section; and

(III) are supervised by a pharmacist who has completed the training specified in §291.26 of this title (relating to Pharmacy Compounding of Sterile Pharmaceuticals), conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy).

(2) - (5) (No Change.)

(e) (No Change.)

§291.33. Operational Standards

(a) *Licensing requirements.*

(1)- (8) (No Change.)

(9) A Class A (community) pharmacy engaged in the compounding of **non-sterile** [sterile] pharmaceuticals shall comply with the provisions of **§291.25 of this title (relating to Pharmacy Compounding of Non-sterile Pharmaceuticals).**

(10) A Class A (community) pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.26 of this title (relating to Pharmacy Compounding of Sterile Pharmaceuticals).

(11) [~~(10)~~] A Class A (Community) pharmacy engaged in the provision of remote pharmacy

services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.20 of this title (relating to Remote Pharmacy Services).

(12) [~~(11)~~] A Class A (Community) pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.37 of this title (relating to Centralized Prescription Dispensing) and/or §291.38 of this title (relating to Centralized Prescription Drug or Medication Order Processing).

(b) *Environment.*

(1) (No Change.)

[~~(2) Special requirements for nonsterile compounding.~~

~~(A) Pharmacies regularly engaging in compounding shall have a designated and adequate area for the safe and orderly compounding of drug products, including the placement of equipment and materials. Pharmacies involved in occasional compounding shall prepare an area prior to each compounding activity which is adequate for safe and orderly compounding.~~

~~(B) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of a drug compounding operation.~~

~~(C) A sink with hot and cold running water, exclusive of rest room facilities, shall be accessible to the compounding areas and be maintained in a sanitary condition. Supplies necessary for adequate washing shall be accessible in the immediate area of the sink and include:~~

~~(i) soap or detergent; and~~

~~(ii) air-driers or single-use towels.~~

~~(D) If drug products which require special precautions to prevent contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for the preparation of other drug products, must be utilized in order to prevent cross-contamination.~~]

(2) [~~(3)~~] *Security.*

(A) - (B) (No Change.)

(3) [~~(4)~~] *Temporary absence of pharmacist.*

(A) - (G) (No Change.)

(c) (No Change.)

(d) *Equipment and supplies.* [~~(1)~~] Class A pharmacies dispensing prescription drug orders shall have the following equipment and supplies:

(1) [~~(A)~~] typewriter or comparable equipment;

(2) [~~(B)~~] refrigerator;

(3) [~~(C)~~] adequate supply of child-resistant, light-resistant, tight, and if applicable, glass containers;

(4) [~~(D)~~] adequate supply of prescription, poison, and other applicable labels;

(5) [~~(E)~~] appropriate equipment necessary for the proper preparation of prescription drug orders; and

(6) [~~(F)~~] metric-apothecary weight and measure conversion charts.

[~~(2) If the community pharmacy compounds prescription drug orders, the pharmacy shall:~~

~~(A) have a Class A prescription balance, or analytical balance and weights which shall be properly maintained and inspected at least every three years by the appropriate authority as prescribed by local, state, or federal law or regulations; and~~

~~(B) have equipment and utensils necessary for the proper compounding of prescription drug orders. Such equipment and utensils used in the compounding process shall be:~~

~~(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;~~

~~(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond acceptable standards;~~

~~(iii) cleaned and sanitized immediately prior to each use; and~~

~~(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance.~~]

(e) (No Change.)

(f) *Drugs.*

(1) - (3) (No Change.)

[~~(4) Drugs, components, and materials used in nonsterile compounding.~~

~~(A) Drugs used in nonsterile compounding shall:~~

~~(i) meet official compendia requirements; or~~

~~(ii) be of a chemical grade in one of the following categories:~~

~~(I) Chemically Pure (CP);~~

~~(II) Analytical Reagent (AR); or~~

~~(III) American Chemical Society (ACS); or~~

~~(iii) in the professional judgment of the pharmacist, be of high quality and obtained from acceptable and reliable alternative sources.~~

~~(B) All components shall be stored in properly labeled containers in a clean, dry area, under proper temperatures as defined in paragraph (1) of this subsection.~~

~~(C) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug product beyond the desired result.~~

~~(D) Components, drug product containers, and closures shall be rotated so that the oldest stock is used first.~~

~~(E) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product.~~]

(4) [~~(5)~~] Class A Pharmacies may not sell, purchase, trade or possess prescription drug samples, unless the pharmacy meets all of the following conditions:

(A) - (D) (No Change.)

(g) - (h) (No Change.)

[~~(i) *Nonsterile compounding.*~~]

~~(1) *Purpose.* The purpose of this subsection is to provide standards for the compounding of nonsterile drug products in licensed pharmacies for dispensing and/or administration to humans or animals. Licensed pharmacies compounding nonsterile drug products shall comply with the following paragraphs in addition to all other provisions of this section and §§291.31, 291.32, 291.34, and 291.35 of this title (relating to Definitions, Personnel, Records, and Triplicate Prescription Requirements).~~

~~(2) *General requirements.*~~

~~(A) Nonsterile drug products may be compounded in licensed pharmacies:~~

~~(i) when there exists a valid pharmacist/patient/prescriber relationship and upon the presentation of a valid prescription drug order; or~~

~~(ii) in anticipation of future prescription drug orders based on routine, regularly observed prescribing patterns.~~

~~(B) Nonsterile compounding in anticipation of future prescription drug orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.~~

~~(i) The pharmacist's professional judgment should be based on criteria such as:~~

~~(I) physical and chemical properties of active ingredients;~~

~~(II) use of preservatives and/or stabilizing agents;~~

~~(III) dosage form;~~

~~(IV) storage conditions; and~~

~~(V) scientific, laboratory, or reference data.~~

~~(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained with the nonsterile compounding record.~~

~~(iii) Any product compounded in anticipation of future prescription drug orders shall be labeled. Such label shall contain:~~

~~(I) name and strength of the compounded medication or list of the active ingredients and strengths;~~

~~(II) facility's lot number;~~

~~(III) "use by" date as determined by the pharmacist using appropriate documented criteria as outlined in clause (i) of this subparagraph; and~~

~~(IV) quantity or amount in the container.~~

~~(C) Commercially available drug products may be compounded for individual patients~~

under the provisions of subparagraph (A) of this paragraph provided the prescribing practitioner has requested that the drug product be compounded.

(D) Drug products may be compounded for the exclusive use of the pharmacy where the products are compounded. Compounded drug products may not be distributed for resale, including distribution to pharmacies under common ownership or control, except that a practitioner may obtain compounded drug products for administration to patients, but not for dispensing. Products compounded for physician administration to patients shall be labeled. Such label shall contain:

(i) the statement: "For Office Use Only";

(ii) name and strength of the compounded medication or list of the active ingredients and strengths;

(iii) facility's control number;

(iv) "use by" date as determined by the pharmacist using appropriate documented criteria as outlined in subparagraph (B)(i) of this paragraph; and

(v) quantity or amount in the container.

(E) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide nonsterile prescription compounding services, but shall not solicit business by promoting to compound specific drug products.

(3) *Compounding process.*

(A) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, any materials involved in the compounding process, and drug products until the condition is corrected.

(B) Personnel engaged in the compounding of drug products shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, hair nets, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.

(C) At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

(D) The pharmacist shall establish and conduct quality control procedures to monitor the output of compounded drug products for uniformity and consistency such as capsule weight variations, adequacy of mixing, clarity, or pH of solutions. Such procedures shall be documented in the nonsterile compounding record.

(E) Compounding records for all drugs compounded in anticipation of future prescription drug orders shall be maintained by the pharmacy electronically or manually as part of the prescription, formula record, formula book, or compounding log and shall include:

(i) the date of preparation;

(ii) facility's lot number;

(iii) manufacturer's lot number(s) and expiration date(s) for all components (if the original manufacturer's lot number(s) and expiration date(s) are not known, the pharmacy shall record the source of acquisition of the components);

(iv) a complete formula, including methodology and necessary equipment;

(v) signature or initials of the pharmacist or supportive person performing the compounding;

(vi) signature or initials of the pharmacist responsible for supervising supportive personnel and conducting in-process and finals checks of compounded products if supportive personnel perform the compounding function;

(vii) the brand name(s) of the raw materials, or if no brand name, the generic name(s) and the name(s) of the manufacturer(s) of the raw materials;

(viii) the quantity in units of finished products or grams of raw materials;

(ix) the package size and the number of units prepared;

(x) documentation of performance of quality control procedures; and

(xi) the criteria used to determine the "use by" date.

(F) Compounding records for all drugs compounded pursuant to an individual prescription and not in anticipation of future prescription drug orders shall be maintained by the pharmacy electronically or manually as part of the prescription, formula record, formula book, or compounding log and shall include:

~~(i) the date of preparation;~~
~~(ii) a complete formula which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) and name(s) of the manufacturer(s) of the raw materials and the quantities of each;~~
~~(iii) signature or initials of the pharmacist or supportive person performing the compounding;~~
~~(iv) signature or initials of the pharmacist responsible for supervising supportive personnel and conducting in-process and finals checks of compounded products if supportive personnel perform the compounding function;~~
~~(v) the quantity in units of finished products or grams of raw materials;~~
~~(vi) the package size and the number of units prepared; and~~
~~(vii) documentation of performance of quality control procedures.~~
~~Documentation of the performance of quality control procedures is not required if the compounding process involves the mixing of two or more commercially available oral liquids or commercially available preparations when the final product is intended for external use.~~]
(i) [~~(j)~~] *Automated devices and systems.*
(1) - (4) (No Change.)

§291.34 Records
(a)-(g) (No Change.)
(h) Other records. Other records to be maintained by a pharmacy:
(1) (No Change.)
(4) suppliers' invoices of dangerous drugs and controlled substances; **a pharmacist** [~~pharmacists or other responsible individuals~~] shall verify that the controlled drugs listed on the invoices were actually received by clearly recording **his/her** [~~their~~] initials and the actual date of receipt of the controlled substances;
(5)-(10) (No Change.)
(j) - (k) (No Change.)